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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,932	02/20/2004	Michael N. Helmus	BSCI-006/00US	9710
22903 7590 07/26/2007 COOLEY GODWARD KRONISH LLP ATTN: PATENT GROUP Suite 500 1200 - 19th Street, NW WASHINGTON, DC 20036-2402			EXAMINER DESAI, ANAND U	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 07/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/781,932	Applicant(s) HELMUS ET AL.	
	Examiner Anand U. Desai, Ph.D.	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-37 is/are pending in the application.
- 4a) Of the above claim(s) 3,8-18,20-24 and 33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30,36 and 37 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 19, 25-29, 31, 34, and 35 is/are rejected.
- 7) ☒ Claim(s) 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to amendment filed on January 23, 2007 and the supplemental amendment filed on May 10, 2007. Claims 6 and 7 have been cancelled. Claims 3, 8-18, 20-24, and 33 have been withdrawn previously. Claims 1, 2, 4, 5, 19, 25-32, and 34-37 are currently pending and are under examination.

Withdrawal of Rejections

2. The rejection of claims 1, 4, 5, 25-32, and 34-37 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn based on the amendment to the claims.
3. The rejection of claim 27, and 34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.
4. The rejection of claims 1, 2, 4, 19, 25, 26, 29, 31 under 35 U.S.C. 102(b) as being anticipated by Cilento et al. (U.S. Patent 4,773,408) is withdrawn based on the amendment to the claims.

Pending Rejections

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1, 2, 4, 5, 26, 28, 31, 34, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Kleinman et al. (Biochemistry 21: 6188-6193 (1982)).

Kleinman et al. describe harvested tumor tissue that comprises type IV collagen (a biocompatible polymer), laminin (a peptide), and heparan sulfate proteoglycan (see entire document, particularly Abstract, and Experimental Procedures, Preparation of Type IV Collagen section).

Response to Remarks

7. Applicants state Kleinman et al. teach isolation and characterization of naturally occurring type II procollagen (appears intended to refer to type IV procollagen), laminin and heparan sulfate proteoglycan from tumor tissue. In contrast, the instant claims are directed to artificial biomaterials. Applicants state Kleinman et al. cannot anticipate the claims as amended because Kleinman et al. do not teach the limitation of artificial biomaterial. Applicant's arguments filed January 23, 2007 have been fully considered but they are not persuasive. The tissue described in Kleinman et al. is isolated so it is an artificial biomaterial no longer in its natural environment. Kleinman et al. describe a composition comprising a biocompatible polymer (collagen) and a bioactive polymer comprising a peptide (laminin an RGD containing peptide, alpha subunit) and heparan sulfate proteoglycan (see entire document, particularly Abstract, and Experimental Procedures, Preparation of Type IV Collagen section).

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8. Claims 1, 2, 4, 5, 19, 25, 26, and 31 stand rejected under 35 U.S.C. 102(e) as being anticipated by Miyamoto (U.S. 2004/0136977 A1).

The rejection was explained in the office action mailed October 23, 2006.

Response to Remarks

9. Applicants state Miyamoto does not describe peptides and proteins as currently claimed because claim 7 was not included in the rejection. Applicant's arguments filed January 23, 2007 have been fully considered but they are not persuasive. Upon review Miyamoto does disclose cell adhesion peptides with RGD sequences. Miyamoto does disclose a material that can comprise fibrin, and/or laminin, which are cell adhesion peptides with RGD amino acid sequences.

10. Claims 27, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Chudzik et al. (U.S. Patent 6,410,044 B1).

Chudzik et al. disclose crosslinkable macromers that can be used as an interface between the tissue site and implant article in a manner sufficient to permit tissue growth through the crosslinked matrix and between the tissue site and implant. The implantable combination comprising a) an implant article selected from the group consisting of tissue implants and prosthetic devices providing a porous surface, and b) a matrix-forming system positioned upon the article and comprising a polymerization initiator and a crosslinkable macromer comprising one or more polymers having pendent polymerizable groups (see Abstract and claim 17).

The polymeric backbone is selected from the group consisting of synthetic macromers, such as polyvinylpyrrolidone (PVP), polyethylene oxide (PEO), and polyethylene glycol (PEG);

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derivatizable naturally occurring polymers such as cellulose; polysaccharides, such as hyaluronic acid, dextran, and heparin; and proteins, such as collagen, gelatin, and albumin (see col. 6, line 64 to col. 7, line 3).

Claim Objections

11. Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

12. Claims 1, 2, 4, 5, 19, 25-29, 31, 34, and 35 are rejected.

13. Claim 32 is objected.

14. Claims 30, 36, and 37 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 20, 2007

/Anand Desai/
Patent Examiner
Art Unit 1656

/Robert B. Mondesi/
Primary Examiner
Group 1652

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